

# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Addiese: COMMISSIONER FOR PATENTS P O Box 1450 Alexandra, Virginia 22313-1450 www.wepto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,755	01/28/2004	Gregory L. Stahl	A0752.70001US01	2264
7590 05/29/2008 Janice A. Vatland Wolf, Greenfield & Sacks, P.C.			EXAMINER	
			VANDERVEGT, FRANCOIS P	
600 Atlantic A Boston, MA 02			ART UNIT	PAPER NUMBER
			1644	
			MAIL DATE	DELIVERY MODE

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Application No. Applicant(s) 10/766,755 STAHL ET AL. Office Action Summary Examiner Art Unit F. Pierre VanderVegt 1644 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 10 December 2007. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-17.22-38.40-62 and 67-74 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 1-13.15.30.32.40-51.57.60 and 62 is/are rejected. 7) Claim(s) 14, 16, 17, 22-29, 31, 33-38, 52-56, 58, 59, 61 and 67-74 is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s)/Vail Date.\_\_\_ Notice of Droftsperson's Fatent Drowing Review (PTO-948).

Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date \_\_\_\_\_\_\_.

5) Notice of Informal Patent Application

6) Other:

Application/Control Number: 10/766,755 Page 2

Art Unit: 1644

### DETAILED ACTION

This application is a divisional of U.S. Application Serial Number 09/464,303, which claims the benefit of the filing date of provisional U.S. Application 60/112,390.

Claims 18-21, 39, 63-66 and 75 have been canceled.

Claims 1-17, 22-38, 40-62 and 67-74 are currently pending.

## Election/Restrictions

 Claim 75 was erroneously included with the inventions of Group II in the restriction requirement mailed October 12, 2006. As a method of screening, it should have been included in Group III, but not in Groups I or II.

In view of Applicant's response filed December 10, 2007 and the interview of October 25, 2007, the restriction between Groups I and II is hereby withdrawn.

Accordingly, claims 1-17, 22-38, 40-62 and 67-74 are the subject of examination in the present Office Action.

## Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-13, 15, 30, 32, 40-51, 57, 60, and 62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to the use of an MBL inhibitor to inhibit lectin complement pathway activation. The claims broadly encompass any type of MBL inhibitor including, but not limited to, peptide-based inhibitors, antibody-based inhibitors, small organic molecules, inorganic molecules, and antisense molecules for example. However, the specification discloses only the possession of peptide-based inhibitors and antibody-based inhibitors at the time the invention was made. See, for example, page 3, line 18 to page 5, line 27 of the specification as originally filed. Applicant is reminded that while

Application/Control Number: 10/766,755

Art Unit: 1644

the claims are to be read in light of the specification, limitations from the specification are not to be read into the claims. Claims are to be given their broadest reasonable interpretation in terms of the scope of what is encompassed by the claims and the instant claims read upon more MBL inhibitors than the peptide-based inhibitors and antibody-based inhibitors disclosed in the specification.

Therefore, only administration of peptide-based or antibody-based MBL inhibitors meet the written description provision of 35 U.S.C. 112, first paragraph. Vas-Cath Inc. v. Mahurkar ((CAFC, 1991) 19 USPQ2d 1111) clearly states that "Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See Vas-Cath at page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). See also the Guidelines for the Examination of Patent Applications under the 35 U.S.C. 112, ¶1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001."

#### Conclusion

- 3. Claims 14, 16, 17, 22-29, 31, 33-38, 52-56, 58, 59, 61 and 67-74 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
- Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571)272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571) 272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Application/Control Number: 10/766,755 Page 4

Art Unit: 1644

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-

direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

F. Pierre VanderVegt, Ph.D. /PV/ Patent Examiner May 23, 2008

/David A Saunders/ Primary Examiner, Art Unit 1644